Establishment Registration & Device Listing

Presented by

Blix Winston, MPA, MS

Chief, Operations Branch, DSMICA

Registration & Listing Purpose

- Required by Federal Food, Drug & Cosmetic Act (law)
- ***Establishment*** Registration - tells FDA where facility is located
- ***Device*** Listing - tells FDA device is in commercial distribution
- Simple notices, not permission or approval

Registration & Listing Process

- Obtain forms
- Mail Registration & Listing forms together (don't fax)
- Keep copies in R&L files at facility
- Update Registration yearly on FDA-2891a (sent out annually by FDA)
- Update Listing information by submitting new listing form, only when changes occur

Obtaining R&L Forms

- FAX: 301-443-8818, Attn: Publications, or…..
- eMail: dsmica@cdrh.fda.gov
  - request R&L forms & instructions
- On Line (Registration form only):
  - http://www.fda.gov/cdrh/reglistpage.html (scroll to Downloadable form 2891)
  - send form to CDRH in triplicate

Initial Registration of Device Establishment - FDA 2891

- Name an “Official Correspondent” (OC)
- OC fills out and mails forms to CDRH
- When to Register
  - Within 30 days of going to market
  - Done one time, updated annually

Initial Registration of Device Establishment - FDA 2891

- How to fill out the form……
  - follow instructions
  - see example on next slide

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

Form Approved: **OMB No. 0910-0387**
Expiration Date: **December 31, 2001.**

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. REGISTRATION NO.

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME			3. RECORD DATE (Mo.)	(Day)	(Year)
MEMORIAL HOSPITAL			12	2	01
4. NUMBER AND STREET	**5. CITY AND FOREIGN STATE**	**6. STATE**	**7. ZIP CODE**		
125 ELM St.	Centerville	MD	20878		
8. FOREIGN COUNTRY	**9. ESTABLISHMENT TYPE** *(See Instruction Booklet)*		**10. PREPRODUCTION REGISTRATION**		
	E M R S T X ID (MB)		☐ YES ☑ NO		

SECTION B

11. OWNER/OPERATOR BUSINESS NAME			12. OWNER/OPERATOR I.D.
XYZ Hospital Group			
13. NUMBER AND STREET	**14. CITY AND FOREIGN STATE**	**15. STATE**	**16. ZIP CODE**
12345 Front St.	CHICAGO	IL	12345
17. FOREIGN COUNTRY	**18. TELEPHONE NUMBER--IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT**		
	312-279-1234		

SECTION C

19. OFFICIAL CORRESPONDENT — 20. REGISTRATION NUMBER

SECTION C

19. OFFICIAL CORRESPONDENT	20. REGISTRATION NUMBER
MARY JONES	

21. BUSINESS NAME: MEMORIAL Hospital

22. NUMBER AND STREET	23. CITY	24. STATE	25. ZIP CODE
125 ELM ST.	Centerville	MD	20878

26. TELEPHONE NUMBER (Area Code)	27. FAX NUMBER (Area Code) (Number)
607-2244 (301)	(301) 607-2266

SECTION D

28. OTHER BUSINESS TRADING NAMES

(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO4	
SO2		SO5	
SO3		SO6	

SECTION E

29. SIGNATURE OF OFFICIAL CORRESPONDENT	30. TITLE
Mary Jones	Dir. Central Supply

Medical Device Listing FDA 2892

- Each device “type” must be listed
  - Models or variations within a type can all be listed on the same form, e.g., oximeter DQA
- Must use original listing form
  - Each form has its own number
  - Not available on CDRH homepage

Medical Device Listing FDA 2892

- Done once, only updated when changes occur
- Submit new listings by themselves
- Keep bottom, yellow copy for your records

Medical Device Listing FDA 2892

- Listing form requires more info than does the Registration form...
  - device classification name (e.g., oximeter) in block 7
  - classification number, (DQA) in block 8

Device Listing

- Uses Owner/Operator (OO) name instead of Establishment name
  - in most cases, OO name will be the same as the Establishment Name

Device Listing

- Classification Name & Number
  - obtain from CDRH Classification database:
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm…..or..
  - CDRH homepage, to Popular Items, to CDRH Databases, to Product Classification Database. Search by keywords, e.g., “oximeter”

Device Listing

- Classification Name = device “type”
- Search results for “oximeter” (1st 4)

1	DQE	2	Catheter, Oximeter, Fiberoptic	870.1230
2	DQA	2	Oximeter	870.2700
3	GLY	2	Oximeter, to meas. Hemoglobin	864.7500
4	DPZ	2	Oximeter, Ear	870.2710

- 3-letter code = Classification #
  - see example on next slide

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0387.
Expiration Date: December 31, 2001.

DEVICE LISTING

Complete and Return to:

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER: C 019120

2. REASON FOR SUBMISSION
- [x] New Listing
- [ ] Update to Device Already Listed
- [ ] Delete Listing

3. REPORT DATE

MO.	DAY	YR.
12	3	01

4. OWNER / OPERATOR ID NUMBER

5. OWNER / OPERATOR NAME: XYZ Hospital Group

6. ADDRESS *(Check [x] if same as submitted on FDA Form 2891)*

a. NUMBER and STREET

b. CITY, STATE, ZIP CODE

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME: OXIMETER

8. CLASSIFICATION NUMBER: DQA

9. PROPRIETARY NAME *(Brand Name)*: MEMORIAL OXIMETER

10. COMMON OR USUAL NAME: OXIMETER

11. **FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS**

a. NAME

b. REGISTRATION NUMBER

11. **FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS**

a. NAME	b. REGISTRATION NUMBER

12. ESTABLISHMENT NAME AND ADDRESS

(Identification of Sites Where Listed Device is Produced)
(Name, Street Number, City, State or Country, ZIP or Postal Code)

REGISTRATION NO.	ESTABLISHMENT TYPE							
	M	R	S	T	X			
A MEMORIAL HOSPITAL (MB)								
B								
C								
D								

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

13. SIGNATURE	14. TYPED OR PRINTED NAME
Mary Jones	

R & L Information

- **Address for forms:**

  FDA

  Device Registration & Listing Branch (HFZ-308)

  9200 Corporate Blvd.

  Rockville, MD 20850-4015

R & L Information

- **Registration & Listing Branch:**
  - **Phone: 301-495-7726**
  - **Fax: 301-495-4660**
  - **(Do *Not* Fax Forms to FDA - Mail them)**

Other Information

- Division of Small Manufacturers, International & Consumer Assistance (DSMICA) - questions about R&L

  1-800-638-2041

- Reuse Homepage
  - http://www.fda.gov/cdrh/reuse/index.shtml

TIPS

- R&L required for all reprocessed SUDs whether or not marketing clearance is required
- Watch the Reuse homepage for new requirements and changes
- Maintain R&L files - if OC leaves, make sure files are still intact